

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

FOREST LABORATORIES, INC., *et al.*,

Plaintiffs,

vs.

COBALT LABORATORIES, INC., *et al.*,

Defendants.

C.A. No. 08-021 (~~GMS~~) (LPS)
(Consolidated)

STIPULATION AND ORDER

The Court, upon the consent and request of Plaintiffs Forest Laboratories, Inc., Forest Laboratories Holdings, Ltd., Merz Pharma GmbH & Co. KGaA, and Merz Pharmaceuticals GmbH (collectively, "Plaintiffs") and Defendants Lupin Pharmaceuticals, Inc. and Lupin Ltd. (collectively, "Lupin"), hereby acknowledges the following Stipulation and issues the following Order.

STIPULATION

1. This Court has subject matter jurisdiction over this patent infringement action (the "Action"). This Court has personal jurisdiction over Plaintiffs and Lupin Pharmaceuticals, Inc. and venue is proper in this Court as to Plaintiffs and Lupin. Lupin Ltd. has agreed that the Court has personal jurisdiction over it, and that venue is proper in this District, only for the purposes of this Action.

2. In this Action, Plaintiffs have charged Lupin with infringement of United States Patent No. 5,061,703 ("the '703 Patent") in connection with Lupin's submission of Abbreviated New Drug Application ("ANDA") No. 90-051 directed to generic tablets containing 5 milligrams or 10 milligrams of memantine hydrochloride per tablet to the U.S. Food and Drug Administration ("FDA").

3. In response to Plaintiffs' charges of patent infringement, Lupin has alleged certain defenses and counterclaims, including that the '703 Patent is invalid and/or not infringed by the generic tablet products containing 5 milligrams or 10 milligrams of memantine hydrochloride that are the subject of ANDA No. 90-051, and that the '703 Patent was improperly listed in the FDA publication *Approved Drug Products with Therapeutic Equivalence Evaluations* (commonly known as the "Orange Book") in connection with Plaintiffs' NAMENDA® brand memantine hydrochloride 5 milligram and 10 milligram tablets and New

Drug Application ("NDA") No. 21-487. No decision has been obtained by either party from this Court regarding these charges of infringement or these defenses and counterclaims.

4. As of the date of this settlement, Lupin has not rebutted the statutory presumption that the '703 Patent is valid and enforceable in this Action. This admission is without prejudice to Lupin's defenses and counterclaims that the '703 Patent is invalid and/or not infringed.

5. Lupin admits that the submission of ANDA No. 90-051 to the FDA for the purpose of obtaining regulatory approval to engage in the commercial manufacture, use and/or sale of generic tablets containing 5 milligrams or 10 milligrams of memantine hydrochloride per tablet within the United States before the expiration of the '703 Patent was a technical act of infringement of that patent under 35 U.S.C. § 271(e)(2)(A). This admission is without prejudice to Lupin's defenses and counterclaims that the '703 Patent is invalid, that the product described by ANDA No. 90-051 does not infringe that patent, and/or that the '703 Patent was improperly listed in the Orange Book in connection with Plaintiffs' NAMENDA® brand memantine hydrochloride 5 milligram and 10 milligram tablets and NDA No. 21-487. This admission is further without prejudice to any claim, defense or counterclaim in any possible future action between Lupin and any of the Plaintiffs regarding the '703 Patent and/or a generic memantine hydrochloride product other than the generic tablet products that are the subject of ANDA 90-051.

6. Both parties have agreed that all other claims, defenses and counterclaims set forth in Plaintiffs' and Lupin's pleadings against each other, including the allegations and averments contained therein, should be dismissed, without prejudice.

ORDER

Accordingly, pursuant to the above Stipulation, and upon the consent and request of Plaintiffs and Lupin, **IT IS HEREBY ORDERED, ADJUDGED AND DECREED THAT:**

1. The filing of ANDA No. 90-051 was a technical act of infringement of the '703 Patent under 35 U.S.C. § 271(e)(2)(A). No decision of the Court has been obtained by either party regarding the presumptive validity of the '703 Patent and/or whether the product described by ANDA No. 90-051 infringes that patent.

2. All other claims, defenses and counterclaims set forth in Plaintiffs' and Lupin's pleadings against each other, including the allegations and averments contained therein, are hereby dismissed, without prejudice.

3. Lupin, its officers, agents, servants, employees and attorneys, and those persons in active concert or participation with them who receive actual notice of this Order by personal service or otherwise, are hereby enjoined from manufacturing, using, offering to sell or selling within the United States, or importing into the United States, the generic tablet products containing 5 milligrams or 10 milligrams of memantine hydrochloride per tablet that are the subject of ANDA No. 90-051 during the life of the '703 Patent, including any extensions and pediatric exclusivities, absent a license agreement or other authorization by Plaintiffs, unless all of the claims of the '703 Patent are found invalid or unenforceable by a court decision from which no appeal has been or can be taken, other than a petition for a writ of certiorari to the U.S. Supreme Court.

4. Plaintiffs and Lupin each expressly waive any right to appeal or otherwise move for relief from this Stipulation And Order.

5. This Court retains jurisdiction over Plaintiffs and Lupin for purposes of enforcing this Stipulation And Order.


6. This Stipulation And Order shall finally resolve this Action between Plaintiffs and Lupin. Should any future litigation arise between Lupin and any of the Plaintiffs regarding the '703 patent and generic tablet products that are the subject of ANDA No. 90-051, the Parties shall be deemed to be in the same position as they were prior to entry of this Order. Further, should any future litigation arise between Lupin and any of the Plaintiffs regarding the '703 Patent and/or generic memantine hydrochloride products, other than the generic tablet products that are the subject of ANDA No. 90-051, each Party shall be free to raise any claim, defense or counterclaim and to argue for its preferred claim construction regarding the '703 patent claims, without prejudice from this Order.

7. This Stipulation And Order is without prejudice to any claim, defense or counterclaim in any possible future action between Lupin and any of the Plaintiffs regarding the '703 Patent and/or a generic memantine hydrochloride product other than the generic tablet products that are the subject of ANDA No. 90-051.

8. The Clerk of the Court is directed to enter this Stipulation And Order forthwith.

SO ORDERED:

This 27th day of September, 200~~8~~¹⁰


~~HONORABLE GREGORY M. SLEET~~
UNITED STATES DISTRICT JUDGE